

REMARKS

I. Status Summary

Claims 1-98 as filed in the instant U.S. patent application were subject to a Restriction/Election Requirement. In response to the Restriction/Election Requirement, Applicants elected the claims of Group II, Claims 14-29 and 49, for prosecution at this time, as well as the sequence of SEQ ID NO. 5 as a sequence upon which the U.S. Patent and Trademark Office (hereinafter the "Patent Office") could initiate a search.

Claims 1-13, 30-48, and 40-98 have been withdrawn from consideration. Claims 14-29 and 49 are pending and have been examined by the Patent Office.

Claims 14-17, 20-29 and 49 have been rejected under the provisions of 35 U.S.C. §112, first paragraph.

Claim 49 has been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,690,926 to Hogan.

Claims 49, 14 and claims dependent therefrom are objected to because the claims are dependent on non-elected claims, and/or attempt to refer to non-elected claims.

Claims 18 and 19 are objected to as being dependent on a rejected base claim. However, the Patent Office has indicated that Claims 18 and 19 would be allowable if rewritten in independent form, including all of the limitations of the base claims and any intervening claims.

Claims 14-29 and 49 have been canceled.

New Claims 99 and 100 represent the subject matter of Claims 18 and 19 but rewritten in independent form, including the limitations of the base claims from which they originally depended. Support for new Claims 99 and 100 can be found in the claims as originally filed. New Claims 99 and 100 do not introduce any new matter.

New claims 101-112 are directed to a particular embodiment of the present invention that the Patent Office has indicated clearly satisfies the provisions of 35 U.S.C. §112, first paragraph (see, the Office Action, at pages 8,

9 and 10). As indicated by the Patent Office in the Office Action, support for the new claims may be found in the claims and specification as filed. New Claims 101-112 do not introduce any new matter.

Reconsideration of the application as amended and based on the arguments set forth herein below is respectfully requested.

II. Response To First 35 U.S.C. §112, First Paragraph Rejection

Claims 14-17, 20-29 and 49 are rejected under 35 U.S.C. §112, first paragraph. The Patent Office states that the claims are rejected for "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, the Patent Office states that the rejected claims embrace "subject matter of variants and/or a genus of vertebrate and/or invertebrate nucleic sequences which are not necessarily related in any way to the disclosed structures of the cloned and purified *Drosophila*, murine and human *piwi* genes, and at best are only required to be similar in functions as a protein that enhances growth, proliferation, and/or self-renewing division of stem cell, which nucleic acid sequences embraces potential genes similar to that of the disclosed *piwi* genes are yet to be discovered."

Respectfully, the Applicant neither agrees nor acquiesces to the foregoing analysis by the Patent Office. The Applicant respectfully notes that "there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." Manual of Patent Examining Procedure, Eighth Edition, Revision 1 (February 2003) (hereinafter "MPEP"), §2163 (I)(A) at page 2100-160, citing In re Wertheim, 191 USPQ 90,97 (CCPA 1976). Consequently, "rejection of an original claim for lack of written description should be rare." MPEP, §2163 (II) (A), at page 2100-163 (*emphasis added*). The Applicant maintains that the disclosure of the specification as filed adequately supports the claims as filed, and conveys to

one of skill in the art that the Applicant was in full possession of the claimed invention at the time of the filing of the application.

However, for the purpose of expediting allowance of subject matter that the Patent Office has indicated to be allowable, Claims 14-17, 20-29 and 49 have been canceled. Accordingly, Applicant respectfully submits that the 35 U.S.C. §112, first paragraph rejection related to written description issues has been rendered moot.

The Patent Office has indicated that the subject matter of the remaining claims (new Claims 99-112) satisfies the written description requirement of 35 U.S.C. §112, first paragraph. Specifically, the Patent Office has stated that Claims 18 and 19 would be allowable if rewritten and resubmitted in independent format. See Official Action at page 13. New 99 represents Claim 18 resubmitted in independent format, while new Claim 100 represents Claim 19 rewritten and resubmitted to depend from new Claim 99. Likewise, the Patent Office has indicated that the as-filed specification provides "sufficient description of the claimed subject matter drawn to an isolated and purified polynucleic acid encoding a biologically active *piwi* family polypeptide, wherein the polynucleic acid is at least about 75% identical to a DNA sequence as set forth in any of SEQ ID NOS: 1, 3, and 5, and wherein the polypeptide comprises the PIWI box." See Official Action at page 8. New Claim 101 is directed to such an embodiment, and new Claims 102-112 are directly or indirectly dependent therefrom.

In view of the foregoing, it is respectfully submitted that the 35 U.S.C. §112, first paragraph written description rejection has been overcome. Accordingly, withdrawal of this rejection is respectfully requested.

III. Response To Second 35 U.S.C. §112, First Paragraph Rejection

Claims 14-17, 20-29, and 49 are rejected under 35 U.S.C. §112, first paragraph. The Patent Office states that the claims are rejected because the specification does not enable any person skilled in the art to which it pertains. . . to make and use the invention commensurate in scope with these claims." In

particular, the Patent Office states that while the specification is enabling "for claims limited to

1/ An isolated and purified polynucleic acid encoding a biologically active piwi family polypeptide, wherein the polynucleic acid is at least about 75% identical to a DNA sequence as set forth in any of SEQ ID NOS: 1, 3, and 5, and wherein the polypeptide comprises the PIWI box.

2/ A recombinant vector comprising the polynucleic acid of 1;

3/ A cultured cell comprising the recombinant vector of 2, . . .

the claimed invention is not supported by a sufficient written description for possessing of the genus of proteins or polypeptides encoded polynucleic acid as recited in the claims, . . . one skilled in the art would not know how to make and used the claimed invention so that it would operate as intended." Official Action at page 10.

While the Applicant respectfully neither agrees nor acquiesces to the foregoing analysis by the Patent Office, Claims 14-17, 20-29 and 49 have been canceled above in the interest of expediting allowance of subject matter that the Patent Office has indicated to be allowable. New Claim 101 is directed to the subject matter of item 1 above; new Claims 102-105 are dependent therefrom. New Claim 106 is directed to the subject matter of item 2 above; new Claims 107-108 are dependent therefrom. New Claim 109 is directed to the subject matter of item 3 above; new Claims 110-100 are dependent therefrom.

The Patent Office having previously indicated that the subject matter of the aforementioned new claims are allowable, withdrawal of the 35 U.S.C. §112, first paragraph enablement rejection is respectfully solicited

IV. Response To 35 U.S.C. §102(b) Rejection

Claim 49 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,690,926 to Hogan. Applicant respectfully does not agree with or acquiesce to the Patent Office's rejection. However, in the interest of expediting prosecution of the instant case, Claim 49 has been canceled.

Accordingly, the Applicant respectfully submits that the rejection under 35 U.S.C. §102(b) has been rendered moot.

V. Response To Objections To The Claims

Claims 49, 14 and claims dependent therefrom are objected to because "the claims are dependent on non-elected claims, and/or attempt to refer to non-elected claims." Claim 49, 14 and claims dependent therefrom have been canceled. Accordingly, the Applicants respectfully submit that this objection with respect to Claim 49, 14 and the claims dependent therefrom has been rendered moot.

Claims 18 and 19 are objected to as being dependent on a rejected base claim. However, the Patent Office has indicated that Claims 18 and 19 would be allowable if rewritten in independent form, including all of the limitations of the base claims and any intervening claims. New Claims 99 and 100 recite the subject matter of Claims 18 and 19 rewritten in independent form, including the limitations of the base claims from which they originally depended. Allowance of new Claims 99 and 100 is respectfully solicited.

CONCLUSIONS

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance. Early passage of the subject application to issue is earnestly solicited.

Should there be any minor issues outstanding in this matter, Examiner Nguyen is respectfully requested to telephone the undersigned attorney.


DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

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